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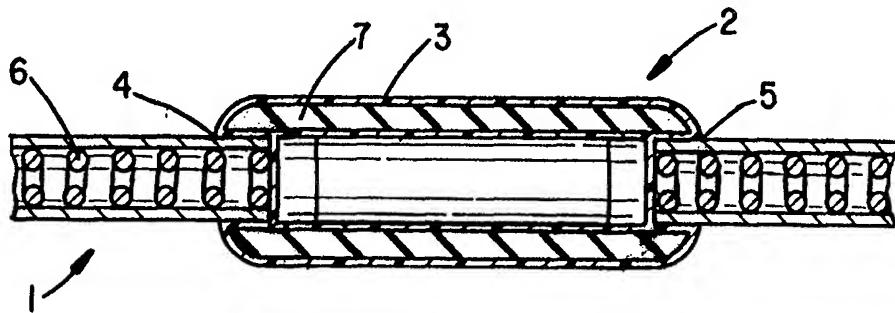
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(54) Title: ADAPTABLE ELECTRODE FOR CORONARY VENOUS LEADS

(57) Abstract

Expendable electrodes (2) for intravascular leads (1) are placed and retained in the vasculature of the left side of the heart. Such electrodes can be in the form of a balloon (3), an expandable wire coil (6), or other expandable shapes (not shown).



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ADAPTABLE ELECTRODE FOR CORONARY VENOUS LEADS

I. Field of the Invention

This invention relates to electrodes for cardiac rhythm management devices such as heart pacemakers and defibrillators. More specifically, this invention relates to electrodes intended to be positioned and retained within one of the cardiac veins in contact with the wall of the vein.

II. Background of the Invention

In recent years it has been determined that various cardiac rhythm anomalies can be effectively treated by applying electrical stimulation pulses to the left side of the heart. In order to provide stimulation pulses to the left side of the heart, it is generally necessary to position an electrode accordingly. Initial efforts to place such an electrode involved highly invasive and traumatic surgery. This surgery required that the chest wall be opened and that an epicardial electrode be sewn or otherwise attached to the heart.

More recently intravascular leads have been developed. The electrode of these leads can be brought into contact with the left side of the heart by advancing the lead through the vena cava, right atrium and coronary sinus into the great vein of the heart. Once there, the electrode can be further advanced toward the apex of the left ventricle through one of the veins that descend from the great vein. See, for example, U.S. Patent Nos. 5,803,928,; 5,755,766; and 5,755,765 and assigned to Cardiac Pacemakers, Inc.

Leads of the type described in the aforementioned '928, '766 and '765 patents offer significant advantages. Such leads provide a suitable electrical path for delivery of pulses from the cardiac rhythm management device to the left side of the heart. Such leads are also capable of sensing electrical signals otherwise associated with the left side of the heart and transferring these signals back to the cardiac rhythm

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management device. More importantly, these leads can be placed without the patient receiving the trauma associated with placing a patch electrode on the exterior of the heart.

5 The efficacy of leads described in the '928, '766 and '765 patents can be enhanced by providing means for ensuring that the electrode associated with the distal end of the lead remains in contact with the vessel wall. Providing a suitable means for ensuring such consistent 10 contact is not easily achieved. The path the lead follows is circuitous and narrow requiring that the lead be very small in diameter and very flexible. Use of a traditional lead fixation device diminishes the flexibility of the lead and increases its diameter.

15 Also, traditional lead fixation devices include tines or other projections which could interfere with advancement of the lead through the vasculature or even damage the vessel wall. Further, sometimes it is necessary to explant a lead for various medical reasons. Thus, the 20 fixation device should be designed to permit the lead to be extracted.

SUMMARY OF THE INVENTION

One object of the present invention is to provide, for use with a cardiac rhythm management device, a lead 25 having an electrode which can be positioned within the vasculature of the heart.

A second object of the invention is to provide such a lead having an electrode which can be positioned in a coronary vein.

30 A third object of the invention is to provide a lead having an electrode which can be positioned in one of the cardiac veins that descends from the great vein toward the apex of the heart.

A fourth object of the present invention is to 35 provide an adaptable electrode which is designed to hold itself in contact with the vein wall.

A fifth object of the invention is to provide an

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adaptable electrode which has a reduced diameter during insertion of the lead and then expands into contact with the vein wall once positioned.

A sixth object of the present invention is to
5 provide an adaptable electrode which is of a size and shape and has sufficient flexibility so that it can pass through a circuitous path having a small diameter.

A seventh object of the invention is to provide an adaptable electrode which can be manipulated to permit
10 extraction of the lead if desired.

These and other objects are achieved by the present invention which provides an electrode and means which cooperate with the electrode to cause the diameter of the electrode to expand and establish firm contact with the
15 vein wall. In one embodiment the electrode is in the form of a mechanical inflation balloon. The balloon contains an osmotically activated material and perforations to allow for the ingress of body fluids into the balloon. As body fluids are commingled with the
20 osmotically activated material, the balloon expands bringing the electrode into contact with the vessel wall.

In a second embodiment, the electrode is a coiled conductive member coupled to a constraining mechanism. When the electrode has been properly positioned, the
25 constraining mechanism is removed so that the coil expands. The constraining mechanism can, for example, be made of a dissolvable material such as mannitol. When the material is dissolved by body fluids, the electrode expands into contact with the vessel wall. The
30 constraining mechanism can also be a sleeve which can be mechanically removed once the electrode is in position.

Other preferred embodiments, features and characteristics of the invention will become apparent from the following detailed description of the invention.

35 **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a cross-sectional view of an electrode incorporating an expandable balloon in the retracted

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position.

Figure 2 is a cross-sectional view of the electrode of Figure 1 with the balloon expanded.

5 Figure 3 is a side view of the electrode shown in figures 1 and 2 with the balloon expanded and showing the perforations through the balloon wall to permit the ingress of body fluids.

Figure 4 is a cross-sectional view of an expandable electrode retained by a dissolvable sleeve.

10 Figure 5 is a cross-sectional view of the electrode of Figure 4 after the sleeve is dissolved.

Figure 6 is a perspective view of the lead shown in Figures 4 and 5 with the restraining sleeve in place.

15 Figure 7 is a perspective view of the lead shown in Figures 4-6 with the restraining sleeve removed.

Figure 8 is a side view of the third alternative lead with the electrode collapsed.

20 Figure 9 is a side view of the third alternative lead with the electrode expanded.

Figure 10 is a side view of a fourth alternative embodiment with the electrode collapsed.

25 Figure 11 is a side view of the lead shown in Figure 10 with the electrode expanded.

Figure 12 is a side view of a fifth embodiment with the electrode collapsed.

Figure 13 is a side view of the lead shown in Figure 12 with the electrode expanded.

30 Figure 14 is a side view of the electrode of the lead shown in Figures 12 and 13.

Figure 15 is a side view of a sixth embodiment with the electrode collapsed.

35 Figure 16 is a side view of the lead shown in Figure 15 with the electrode expanded.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

35 Figures 1-3 show a first embodiment of the invention. As shown, this embodiment includes an elongated lead body 1 and an electrode 2. The electrode

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2 is in the form of a balloon 3 coupled at its proximal end 4 and its distal end 5 to the lead body 1. So that it can conduct electricity, the balloon 3 is made of a polymer such as polytetrafluoroethylene and coated with a 5 conductive material by vapor deposition or other means for depositing a thin conductive layer on a polymer substrate. The balloon 3 is also coupled to a conductive coil 6 which extends from the proximal end of the lead past the balloon electrode 3 to provide a conductive path 10 from the balloon electrode 3 to the proximal end of the lead.

The balloon 3 is filled with an inflation material which expands when it comes into contact with body fluids. Suitable materials will typically comprise a 15 hydrophilic polymer that may be treated by a pharmacological, osmotically active agent. For example, the inflation material could be silicone rubber interlaced with sodium chloride, glycerol or any other non-toxic, water soluble material that does not adversely 20 affect the curing of the water permeable polymer (silicone rubber). Silicone rubber is known for its hydrophilic characteristics. Likewise, the presence of an osmotically active agent will cause body fluids to penetrate the balloon 3 and come into contact with the 25 silicone rubber. Body fluids enter the balloon 3 through the orifices such as 8 shown in Figure 3. Once the electrode 3 is exposed to the body fluids, the body fluids enter the orifices 8 to expand the balloon 3 by activation of the osmotic agent within the hydrophilic 30 material 7 until the balloon electrode 3 comes into contact with the vessel wall.

A second embodiment of the present invention is shown in Figures 4-7. These figures show an elongated lead body 1 and an electrode 2. The electrode in this 35 embodiment is an expandable coil 3 coupled at its proximal end 4 to the coil 6 that runs from the electrode 2 to the proximal end of the lead. As in the first

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embodiment, an insulative material covers the conductive coil 6.

Figure 4 also shows a retaining sleeve 10 covering the expandable coil 3. The retaining sleeve 10 is 5 provided to restrict the diameter of the expandable coil 3 until the lead is properly positioned. The sleeve 10 can then be mechanically removed. Alternatively, the sleeve 10 is made of a material that is dissolved by body fluids such as mannitol. After the sleeve 10 is removed, 10 either mechanically or as a result of being dissolved by body fluids, the coil 3 will expand to the shape shown in Figure 5 and into firm, fixed contact with the vessel wall.

Figures 8 and 9 show another embodiment including a 15 lead body 1 and electrode 2. The lead body 1 incorporates an outer member 11 and an inner member 12 that projects past the outer member 11 to form a tube within a tube arrangement. The electrode 2 is a coil 3 coupled at its distal end 5 to the inner member 12 and at 20 its proximal end 4 to the outer member 11. A comparison of Figures 8 and 9 show that the coil 3 can be expanded or retracted by sliding the outer member 11 over the inner member 12. As the outer member 11 is slid distally over the inner member, the coil 3 expands as shown in 25 Figure 9. As the outer member is slid proximally over the inner member, the coil retracts as shown in Figure 8.

The embodiment shown in Figures 10 and 11 is similar to that shown in Figures 8 and 9. Instead of the outer member 11 sliding over the inner member 12, the inner 30 member and outer member are rotated with respect to each other. When rotated in one direction, the coil 3 expands to the position shown in Figure 11. When rotated in the opposite direction, the coil 3 retracts to the position shown in Figure 10.

35 Figures 12-14 show the preferred embodiment of a lead having a bipolar configuration incorporating a lead body 21, a first ring electrode 22 of a standard

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configuration and an adaptable electrode 23. The adaptable electrode 23 includes a coiled section 24, an elongated section 25 and an actuation member 26. When assembled, the adaptable electrode is positioned so that 5 the elongated section 25 is positioned within a lumen (not shown) of the lead body 21 so that the actuation member 26 extends from the proximal end of the lead body and the coiled section 24 extends out of the lead body 21 through an orifice 30 that extends from the lumen to the 10 exterior of the lead. The distal end 35 of the coiled section 24 can be fixed to the lead body 21 by a ring 36. Thus, by pulling on the actuation member 26 one can 15 retract the coil into the position shown in Figure 12. By pushing the actuation member 26 one can extend coil 23 to assume the expanded helix position shown in Figure 13. Both the ring electrode 22 and the coil electrode 23 can be coupled to the cardiac rhythm management device to provide bipolar therapy via the lead. Alternatively, one 20 electrode can be used for sensing while the other is used for applying therapeutic stimulations to the heart.

Another bipolar lead configuration incorporating the present invention is shown in Figures 15 and 16. In this embodiment the lead consists of a lead body 50, a ring electrode 51 and an elongate electrode 52. The elongate 25 electrode 52 is attached at its distal end 53 to a ring 54 and passes through an orifice 55 through a lumen (not shown) and extends past the proximal end of the lead. The proximal end of the elongate electrode 52 is coupled to an actuation member 56. Pulling on the actuation 30 member 56 causes the elongate lead to assume the position shown in Figure 15. Pushing the actuation member causes the lead to assume the position shown in Figure 16 and engage the vessel wall into which the lead is inserted.

The coil 3 can be constructed in a number of 35 different ways. It can be formed of a round wire, a ribbon-shaped wire, a coil consisting of a plurality of wires, a braided cable or the like. The coil 3 can also

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be coated with a hydrophilic coating, polytetrafluoroethylene (PTFE), or silicone. A variety of materials can be used for the coil 3, but the preferred material is nickel-titanium.

5 The foregoing description of various embodiments has been provided to comply with disclosure requirements of the patent laws. This disclosure is not intended to be limiting. Instead, the scope of the invention is defined by the following patent claims which are to be
10 interpreted to include a full range of equivalents.

What is claimed:

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CLAIMS

1. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:
 - a. a lead body;
 - b. an electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and
 - c. adaptation means for causing said electrode to move from said first retracted position to said second extended position.
2. The cardiac lead of claim 1 wherein said electrode is a balloon and said adaptation means includes a water-permeable material within the balloon that reacts with body fluids to cause the balloon to expand by the osmotic process.
3. The cardiac lead of claim 2 wherein said balloon has perforations which allow body fluids to penetrate the balloon.
4. The cardiac lead of claim 2 wherein said water permeable material includes silicone rubber and wherein said osmotic agent includes a material selected from a group consisting of sodium chloride, glycerol, dexamethasone, sodium phosphate or potassium chloride.
5. The cardiac lead of claim 4 wherein said osmotic agent comprises a pharmacological agent.
6. The lead of claim 2 wherein said water-permeable material is hydrophilic.
7. The lead of claim 2 wherein said water-permeable material includes a hydrophilic substance treated with an osmotically active agent.
8. The cardiac lead of claim 1 wherein said adaptation means is a sleeve that surrounds the electrode holding the electrode in the first retracted position and wherein removal of the sleeve causes the electrode to

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assume the second extended position.

9. The cardiac lead of claim 8 wherein said sleeve is removed by subjecting it to body fluids which cause the sleeve to dissolve.

5 10. The cardiac lead of claim 9 wherein said sleeve is made of mannitol.

11. The cardiac lead of claim 1 wherein said electrode includes a coil.

10 12. The cardiac lead of claim 11 wherein said electrode coil is comprised of round wire.

13. The cardiac lead of claim 11 wherein said electrode coil is comprised of ribbon wire.

14. The cardiac lead of claim 11 wherein said electrode coil is made of nickel-titanium.

15 15. The cardiac lead of claim 11 wherein said adaptation means includes an outer member that surrounds a portion of the lead body, said lead body extending beyond said outer member and said electrode coupled to said lead body and said outer member.

20 16. The cardiac lead of claim 15 wherein said electrode moves between said first retracted position and said second extended position by sliding the outer member relative to the lead body.

25 17. The cardiac lead of claim 15 wherein said electrode moves between said first retracted position and said second extended position by rotating the outer member relative to the lead body.

30 18. The cardiac lead of claim 1 wherein said lead body included a lumen and an orifice extending between the lumen and the exterior of the lead.

19. The cardiac lead arrangement of claim 18 wherein said electrode has a distal end fixed to the exterior of said lead body and extends through said orifice into said lumen.

35 20. The cardiac lead arrangement of claim 19 wherein said electrode is comprised of coil or braided cable.

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21. The cardiac lead arrangement of claim 11 wherein said electrode coil is made from round or ribbon wire.

5 22. The cardiac lead arrangement of claim 21 wherein said electrode coil material is NiTi.

10 23. The cardiac lead arrangement of claim 19 wherein said adaptation means includes a member coupled to said electrode extending from the lead so that one can apply a force to said member to cause the lead to move between said retracted and extended positions.

24. The cardiac lead arrangement of claim 23 wherein said member coupled to said electrode is a coil of round or ribbon wire.

15 25. The cardiac lead arrangement of claim 24 wherein said coil is coated with a coating selected from a group consisting of polytetrafluoroethylene, silicone, and any other hydrophilic material.

AMENDED CLAIMS

[received by the International Bureau on 07 February 2000 (07.02.00); original claims 1, 8-12 and 21 cancelled; original claims 2, 3, 13-15, 18 and 22 amended; remaining claims unchanged (3 pages)]

1. Cancel
2. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:
 - a. a lead body;
 - b. a balloon electrode having a first retracted position and a second expanded position in which said balloon electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and
 - c. a water-permeable material within the balloon electrode that reacts with body fluids to cause the balloon electrode to expand by the osmotic process for causing said balloon electrode to move from said first retracted position to said second extended position.
3. The cardiac lead of claim 2 wherein said balloon electrode has perforations which allow body fluids to penetrate the balloon electrode.
4. The cardiac lead of claim 2 wherein said water permeable material includes silicone rubber and wherein said osmotic agent includes a material selected from a group consisting of sodium chloride, glycerol, dexamethasone, sodium phosphate or potassium chloride.
5. The cardiac lead of claim 4 wherein said osmotic agent comprises a pharmacological agent.
6. The lead of claim 2 wherein said water-permeable material is hydrophilic.
7. The lead of claim 2 wherein said water-permeable material includes a hydrophilic substance treated with an osmotically active agent.
8. Cancel
9. Cancel
10. Cancel
11. Cancel
12. Cancel

13. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:

- a. a lead body;
- b. a ribbon wire coil electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and
- c. adaptation means for causing said electrode to move from said first retracted position to said second extended position.

14. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:

- a. a lead body;
- b. a nickel-titanium coil electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and
- c. adaptation means for causing said electrode to move from said first retracted position to said second extended position.

15. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:

- a. a lead body;
- b. a coil electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and
- c. an outer member that surrounds a portion of the lead body, said lead body extending beyond said outer member and said coil electrode coupled to said lead body and said outer member for causing said coil electrode to move from said first retracted position to said second extended position.

16. The cardiac lead of claim 15 wherein said electrode moves between said first retracted position and said second extended position by sliding the outer member relative to the lead body.

17. The cardiac lead of claim 15 wherein said electrode moves between said first retracted position and said second extended position by rotating the outer member relative to the lead body.

18. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:

a. a lead body including a lumen and an orifice extending between the lumen and the exterior of the lead;

b. an electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and

c. adaptation means for causing said electrode to move from said first retracted position to said second extended position.

19. The cardiac lead arrangement of claim 18 wherein said electrode has a distal end fixed to the exterior of said lead body and extends through said orifice into said lumen.

20. The cardiac lead arrangement of claim 19 wherein said electrode is comprised of coil or braided cable.

21. Cancel

22. A cardiac lead positionable within the vasculature of the heart for use in conjunction with a cardiac rhythm management device, said cardiac lead comprising:

a. a lead body;

b. a round or ribbon wire NiTi coil electrode having a first retracted position and a second expanded position in which said electrode is in contact with a vessel wall when the lead is positioned within the vasculature of the heart; and

c. adaptation means for causing said coil electrode to move from said first retracted position to said second extended position.

23. The cardiac lead arrangement of claim 19 wherein said adaptation means includes a member coupled to said electrode extending from the lead so that one can apply a force to said member to cause the lead to move between said retracted and extended positions.

24. The cardiac lead arrangement of claim 23 wherein said member coupled to said electrode is a coil of round or ribbon wire.

25. The cardiac lead arrangement of claim 24 wherein said coil is coated with a coating selected from a group consisting of polytetrafluoroethylene, silicone, and any other hydrophilic material.

STATEMENT UNDER ARTICLE 19(1)

The replacement pages contain changes to the claims as follows:

Claim 1 has been cancelled since it covers embodiments in art cited in the search report.

Claim 2 has been amended to combine the features of claims 1 and 2 of the originally filed claims.

Claim 3 has been amended to add the word "electrode" after the word --balloon--.

Claims 4-7 are unchanged.

Claims 8-12 have been cancelled since they cover embodiments in art cited in the search report.

Claim 13 has been amended to combine the features of claim 1, 11 and 13 of the originally filed claims.

Claim 14 has been amended to combine the features of claim 1, 11 and 14 of the originally filed claims.

Claim 15 has been amended to combine the features of claim 1, 11 and 15 of the originally filed claims.

Claims 16 and 17 are unchanged.

Claim 18 has been amended to combine the features of claim 1 and 18 of the originally filed claims.

Claims 19 and 20 are unchanged.

Claim 21 has been cancelled.

Claim 22 has been amended to combine the features of claim 1, 11 and 21 of the originally filed claims.

Claims 23-25 are unchanged.

The amended claims are believed to be within the scope of the invention described in the specification as only combinations of the previously filed claims have been made to define the invention without reading on the cited art in the search report.

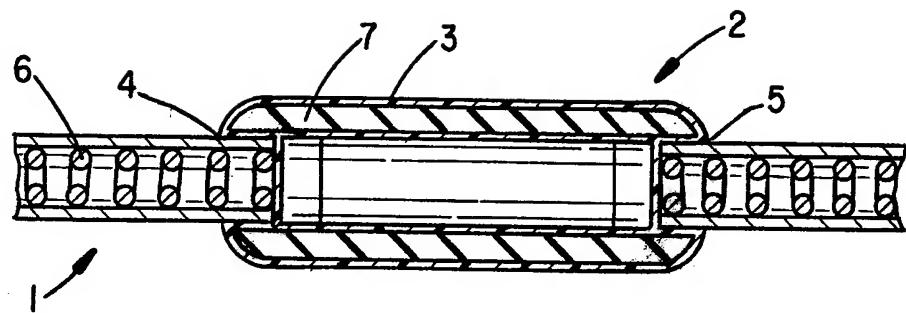


FIG. 1

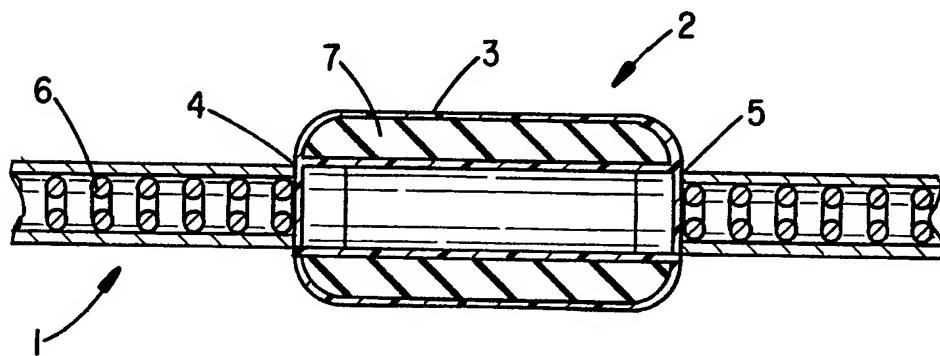


FIG. 2

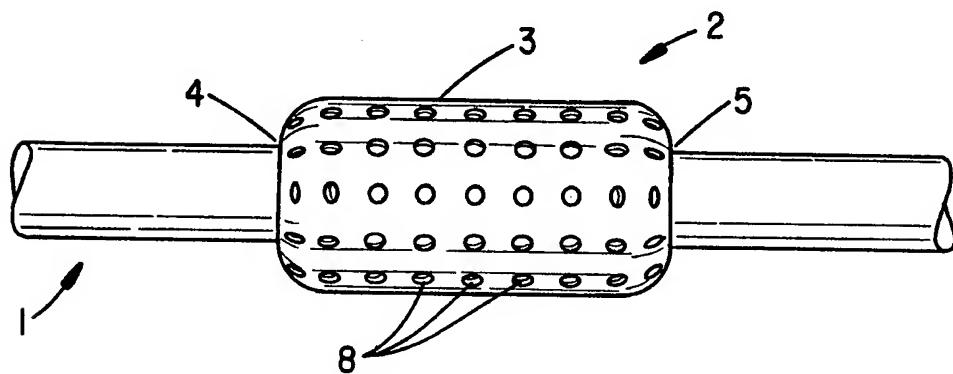


FIG. 3

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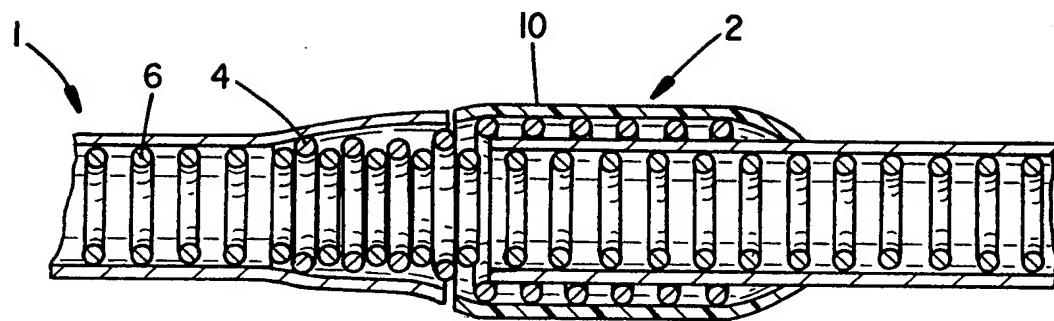


FIG. 4

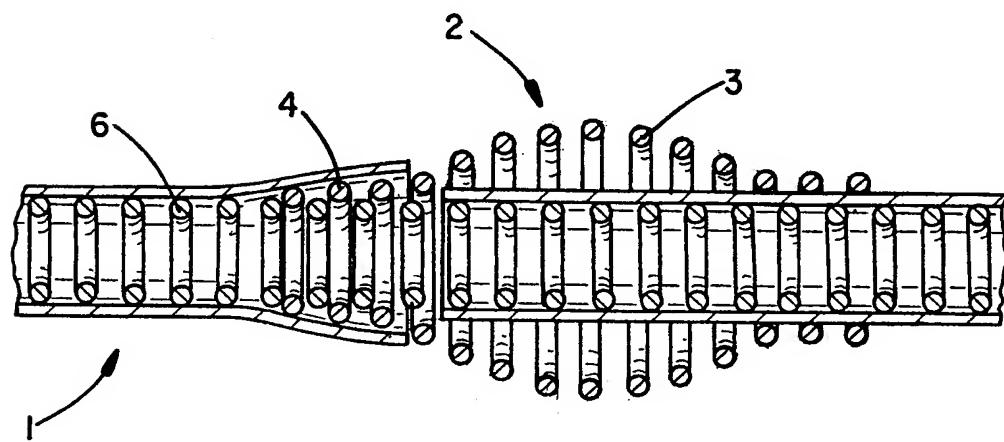


FIG. 5

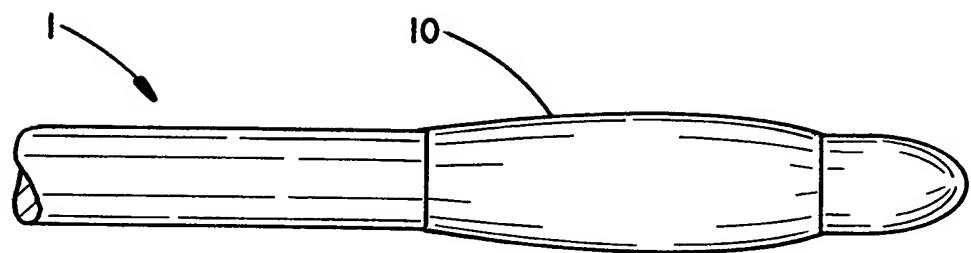


FIG. 6

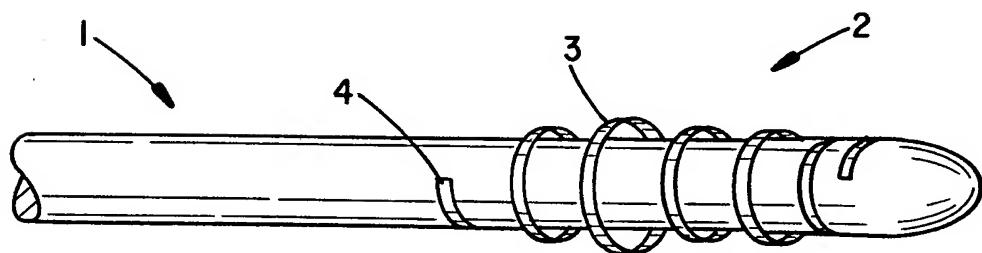


FIG. 7

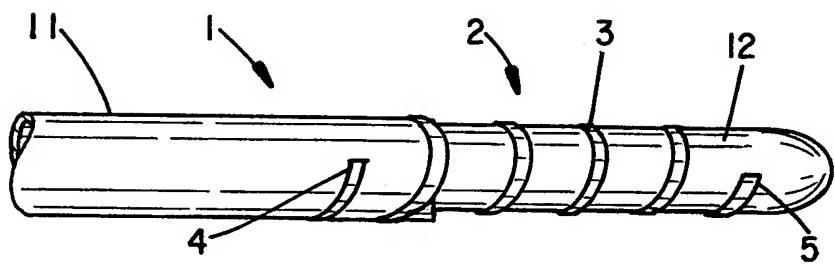


FIG. 8

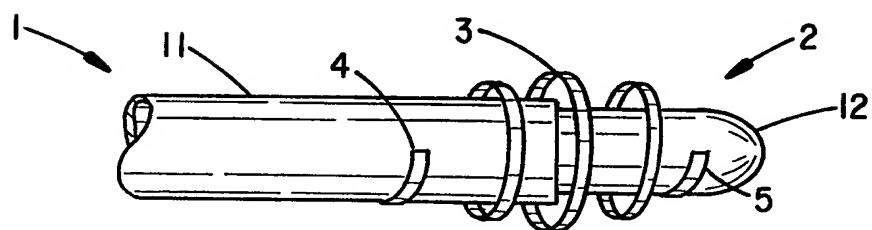


FIG. 9

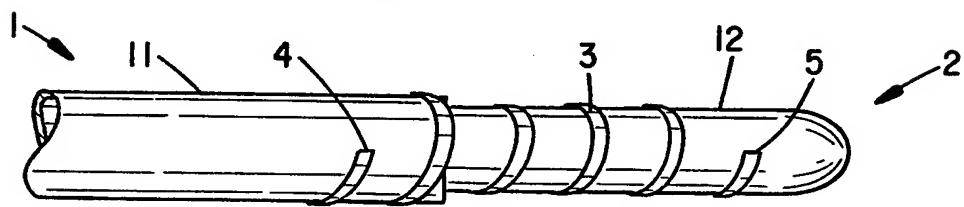


FIG. 10

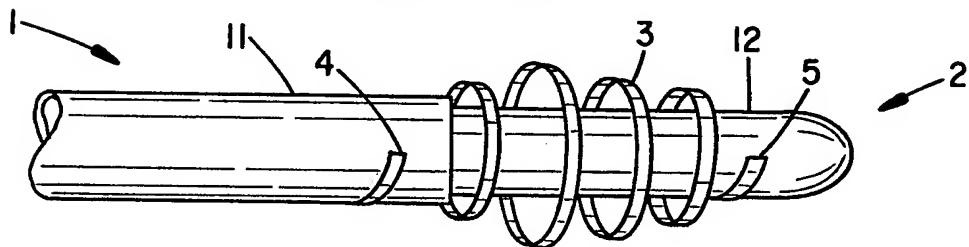


FIG. 11

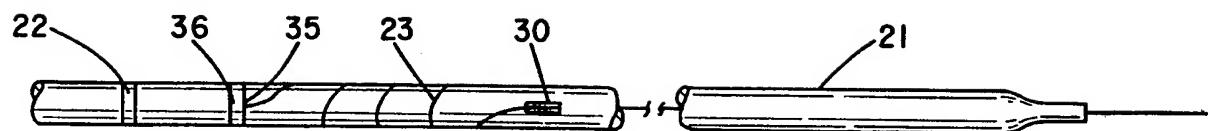


FIG. 12

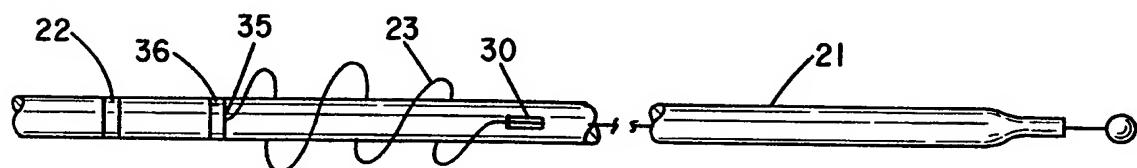


FIG. 13

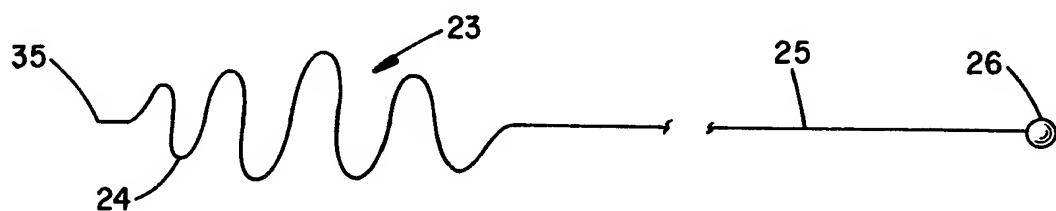
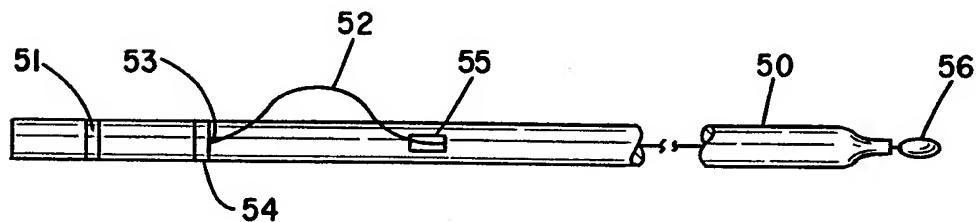
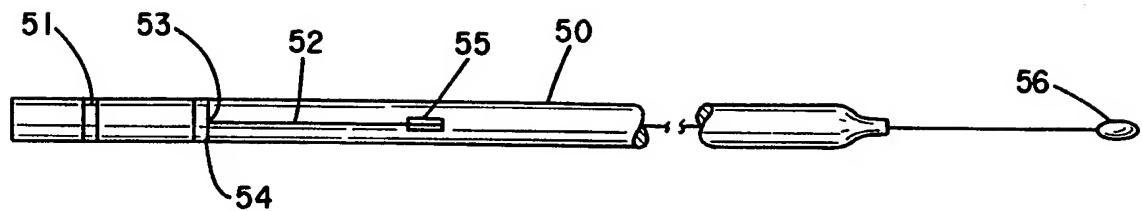


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US99/24374

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 1/05

US CL :600/374, 375; 607/122, 126

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/122, 126; 600/374, 375

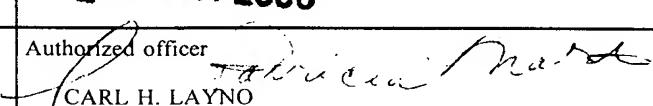
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| X | US 5,170,802 A (MEHRA) 15 December 1992, Figs.1-4, and col.3 line 40. | 1, 8, 11, 12, 21 |
| X,P | US 5,954,761 A (MACHEK et al) 21 September 1999, Figs.1, 3, 7 and 10, col. 4 lines 7-10, and col. 5 lines 42-50. | 1, 8-10 |
| A,P | US 5,860,974 A (ABELE) 19 January 1999, entire document. | 1-3 |
| A,P | US 5,951,597 A (WESTLUND et al.) 14 September 1999, Figs.1 and 2. | 1 |

Further documents are listed in the continuation of Box C. See patent family annex.

| | | |
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| * Special categories of cited documents: | | |
| "A" document defining the general state of the art which is not considered to be of particular relevance | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "E" earlier document published on or after the international filing date | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
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| "O" document referring to an oral disclosure, use, exhibition or other means | | |
| "P" document published prior to the international filing date but later than the priority date claimed | "&" | document member of the same patent family |

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|---|---|
| Date of the actual completion of the international search 03 JANUARY 2000 | Date of mailing of the international search report 19 JAN 2000 |
| Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230 | Authorized officer  CARL H. LAYNO Telephone No. (703) 308-3694 |
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